

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA)
)
)
v.)
) NO.: 2:13-CR-56
)
ANINDYA KUMAR SEN and)
PATRICIA POSEY SEN)

MEMORANDUM AND ORDER

On June 11, 2013, the federal grand jury returned a 38-count indictment charging Anindya Kumar Sen and Patricia Posey Sen (referred to herein collectively as “the Sens” or individually as “Dr. Sen” or “Mrs. Sen” or “defendant”) and East Tennessee Cancer & Blood Center, PC, (“ETCBC”), with offenses related to the use of misbranded drugs in Dr. Sen’s medical practice. Count One charged the defendants with conspiracy to commit offenses against the United States, i.e., causing the introduction into interstate commerce of misbranded drugs with the intent to defraud and mislead in violation of 21 U.S.C. §§ 331(a) and 331(a)(2) and fraudulently and knowingly importing and bringing into the United States merchandise contrary to law in violation of 18 U.S.C. § 545. Counts Two through Thirty charged the Sens with causing, or aiding and abetting, the introduction into interstate commerce of misbranded drugs within intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a), 333(a)(2), 352(f)(1), 352(o), 360(j), 353(b)(4)(A) and 18 U.S.C. § 2. Counts Thirty One through Thirty Seven charged the defendants with receiving merchandise imported contrary to law in violation of 18

U.S.C. § 545 and 2. Count Thirty Eight charged defendants with conspiracy to commit healthcare fraud in violation of 18 U.S.C. § 1349.

A superseding indictment returned by the grand jury on July 9, 2013, added two counts charging Mrs. Sen with making false material statements in violation of 18 U.S.C. § 1001. On October 8, 2013, the grand jury returned a second superseding indictment. The second superseding indictment dropped the conspiracy charge from Count One of the original indictment, charged Dr. Sen with misdemeanor violations of § 331 in Counts One through Twenty Nine (dropping the felony charges originally lodged against Dr. Sen), charged Mrs. Sen and ETCBC in the same counts with felony violations of §§ 331(a) and 333(a)(2); and charged Mrs. Sen and ETCBC in Counts Thirty through Thirty Six with receiving merchandise imported contrary to law in violation of 18 U.S.C. § 545. Mrs. Sen and ETCBC were charged in Counts Thirty Seven through Eight One with health care fraud in violation of 18 U.S.C. § 1347. Counts Eighty Two and Eighty Three charge Mrs. Sen with violations of 18 U.S.C. § 1001. All charges against ETCBC were dismissed upon motion of the United States on November 19, 2013. A third superseding indictment was returned on the same day charging the defendants, except for ETCBC, with the same offenses in the same counts as the second superseding indictment.

After a jury trial, Dr. Sen was convicted on December 12, 2013, of the charges in Counts One through Twenty Nine of the third superseding indictment. Mrs. Sen was convicted of a lesser included offense in Counts One through Twenty Nine, that is, the same misdemeanor offenses as her husband, Dr. Sen. Mrs. Sen was found not guilty as to all other felony counts of the third superseding indictment. Both defendants have made numerous objections to the presentence reports (“PSR”) prepared by the United States Probation Office. The Court heard additional proof and arguments related to the objections on April 30, 2014. This order will

address defendants' objections. The PSR prepared for Dr. Sen found the offense level to be 6, his criminal history category to be I, and an advisory guidelines range of zero to six months. The advisory guidelines range for a fine was determined to be \$500 to \$2,900,000, with a statutory maximum fine of \$100,000 per count. As to Mrs. Sen, the probation officer determined the offense level to be 30, the criminal history category to be I, and the advisory guidelines range to be 97 to 121 months of imprisonment. The advisory range for a fine was determined to be \$15,000 to \$150,000. Mrs. Sen likewise faces a maximum term of imprisonment of one year and a \$100,000 statutory maximum fine as to each count.

I. Dr. Sen's Objections

Dr. Sen has filed 53 separately numbered objections to the PSR. First, Dr. Sen objects to paragraphs 10 through 80 of the PSR which outline the offense conduct.¹ He objects to paragraph 86 which found a base offense level of 6, arguing that the base offense level should be lower than 6 because the PSR fails to account for USSG § 2N2.1, App. note 1 and that he qualifies for a role adjustment as a "minimal participant" under USSG § 3B1.2(a). Dr. Sen objects to paragraphs 133 and 141 because they fail to note what Dr. Sen sees as a "Constitutional bar on imprisonment for crimes that do not require proof of a *mens rea*." Dr. Sen also objects to the fine range stated in paragraph 143, arguing that the range pursuant to USSG § 5E1.2(c)(3) is \$500 to \$5,000. Finally, he objects to the conclusion of the probation office in paragraphs 149 and 150 that "[t]he Probation Officer has not identified any factors" that would

¹ Dr. Sen also objects to paragraph 3 of the PSR which outlines some of the procedural history set forth above. He objects because the paragraph does not mention that the second superseding indictment explicitly removed from the indictment all felony charges against Dr. Sen. If the PSR does not explicitly state that all felony charges were dismissed voluntarily by the government, it certainly implicitly does so and the Court is fully aware that Dr. Sen was not convicted of any felony offenses based on a jury finding that he had acted with either knowledge or intent to defraud.

warrant a departure or variance. The Court will address each objection or set of objections in turn.

A. The Offense Conduct

The objections to the probation officer's recitation of the offense conduct can largely be characterized, with a few exceptions, as "advocacy objections," that is, an attempt by the defendant to put the information contained in those paragraphs in a light more favorable to him. He generally argues that the offense conduct paragraphs "demonstrate substantial bias, likely as a result of the Probation Officer obtaining . . . information provided by the government," and are factually inaccurate, incomplete, misleading or irrelevant to Dr. Sen. The Court, with a few minor exceptions noted below, will not decide these objections. The Court presided over the trial, heard all the testimony, and has read the trial transcript in preparation for sentencing. The Court will rely on its own recollection of the evidence in the case to the extent any of these factual disputes are relevant to sentencing and will not simply rely on the probation officer's recitation of the facts. *See Fed. R. Crim. P. 32(i)(3)(B).* The Court will briefly address the specific objections made by Dr. Sen that some portions of the offense conduct section of the PSR are inaccurate because they conflict with the actual trial testimony.

1. Paragraph 27 (Objection No. 17). Dr. Sen argues that the statement in this paragraph that "the invoices began listing a country of origin or distribution, along with the name of the drug" is inaccurate and should say that the invoices simply listed a country. That the country listed on the invoice was one of origin or distribution is a reasonable inference the fact-finder could, and apparently did, draw from the evidence. This objection is OVERRULED.

2. Paragraphs 41, 44, 45 and 46 (Objection Nos. 21, 22, 23 and 24).

These objections are almost identical to the objections raised as to paragraph 27 and are OVERRULED for the same reasons.

3. Paragraph 49 (Objection No. 27). Dr. Sen objects to the statements in paragraph 49 that Torri Emmette testified that she “specifically remembered the drug Altuzan and that Altuzan/Avastin was one of the drugs for which she could not read the label or the insert” because it was in a foreign language. The Court agrees with Dr. Sen that Torri Emmette’s trial testimony was different. She testified, in response to questions from the government attorney, that she had seen drug packages “with languages other than English on the labels,” and package inserts “with language other than English.” With respect to what drug names had foreign languages on the package labeling, however, Emmette responded “I don’t recall which ones had it and which ones did not.” [Doc. 142, pg. I.D. #s 1880-81]. This objection is SUSTAINED.

The Court does note, however, that Barbara Henaker, Amy Cobble and Kristy Cutshaw, all of whom worked as chemotherapy nurses at Dr. Sen’s medical practice, identified a number of drugs that came with foreign language on the packaging or packaging inserts, including Genzar, Rituxan, Rituxamab, Herceptin, Venofer, Zometa, Erbitux, Abraxmane, Hycamtin, and Taxotere.

4. Paragraph 53 (Objection No. 29). Dr. Sen objects to the last sentence of this paragraph. So far as the Court can determine, Kristy Cutshaw did not testify at trial that “Posey Sen want[ed] extra drugs to be ordered in anticipation of delays caused by the royal wedding.” This objection is SUSTAINED.

5. Paragraph 56 (Objection No. 31). This paragraph of the PSR references the testimony of Amy Cobble at trial. Dr. Sen objects to two statements based on Cobble’s trial testimony as inaccurate: (1) “Cobble knew that Posey Sen closely monitored the costs of the chemotherapy drugs,” and (2) “Posey Sen would tell the nurses what drugs they could order from Oncology Supply and what drugs Posey Sen wanted to order from the other supplier.” The Court agrees that these statements do not track the trial testimony of Cobble and the objection is SUSTAINED as to these inaccurate statements.

The Court also notes, however, that the facts set forth in the paragraph and the “skew” that the probation officer has placed on them, do accurately reflect the testimony of other witnesses. For instance, Torri Emmette testified that “Trish” oversaw the day-to-day operations of the clinic and was responsible for ordering drugs for the clinic. Barbara Heneger’s testimony confirmed that. According to Heneger, “Trish” told the nurses that she was ordering from Clinical Care and “that she was just getting a better price on the drugs.” Mrs. Sen further instructed the nurses that they “were not to order anything [from Oncology Supply] that she got from Clinical Care without speaking to her first.” Heneger also confirmed that she never talked to Dr. Sen about these matters, believing he was aware of them. She further testified that Dr. Sen deferred to his wife, the practice manager, when he was approached about these matters, directing the nurses to “talk to Trish.”

6. Paragraph 61 (Objection No. 33). Dr. Sen asserts that this paragraph contains misstatements of fact. The only part of the paragraph specifically objected to, however, has to do with the last sentence. Melissa White testified that if the Johnson City location of Dr. Sen’s practice needed drugs that were to be ordered from Clinical Care, a list of the drugs needed was sent to the Greeneville office. When the drugs were received from Clinical Care, they were

usually brought to the Johnson City location by employee Julia Vanswarigen, who came there when Dr. Sen was seeing patients. The PSR states: “On the occasions when Vanswaringen did not accompany Kumar Sen, Kumar Sen brought drugs from Greeneville to Johnson City. However, when he transported the drugs, Kumar Sen would have someone from the Johnson City office retrieve the drugs from his car.” Dr. Sen claims that White “did not testify, that Dr. Sen repeatedly brought drugs to the Johnson City clinic.” True that may be, but that is not what paragraph 61 says. Ms. White did respond to the following questions from the government attorney: “Q. What if any occasions do you recall when Dr. Sen brought the drugs from Greeneville to Johnson City? A. It may have been just one time. We would go to the car and get it out and bring it in if no one else was coming.” This objection is OVERRULED.

7. Paragraph 63 (Objection No. 35). Dr. Sen asserts that there is no basis in the record for many of the factual assertions made in this paragraph. He specifically objects to the probation officer’s characterization about what Melissa White testified to at trial. White clearly did testify that J.T. was a patient at the Johnson City clinic who suffered from colon cancer and was prescribed Avastin. Ms. White did not testify that J.T. was still receiving chemotherapy in early 2012 and died in early 2013. To that extent, the objection is SUSTAINED.

8. Paragraph 64 (Objection No. 36)². Again, Dr. Sen claims this paragraph is a mischaracterization of Ms. White’s testimony. Ms. White testified that there was a time when “the other girls [in the Johnson City clinic] were checking the PYXIS medication machine to see if all the medications had NDC numbers on them,” that some did not, and that these were

² Dr. Sen’s objection refers to paragraph 65. Given the content of the objection, he is almost certainly referring to paragraph 64.

sent back to Greeneville with Vanswaringen. To the extent paragraph 64 is inconsistent with the above summary of White's testimony, Dr. Sen's objection is SUSTAINED.

9. Paragraph 67 (Objection No. 37). Dr. Sen objects to the PSR's statement that "Vanswaringen recalled drug boxes with foreign languages on the labels," arguing that her testimony at trial was just the opposite. The record does not support Dr. Sen's position. Vanswaringen testified that she saw an insert with foreign language on it in the chemotherapy room when she was cleaning up. She further testified that she did not see the boxes before she left Greeneville for Johnson City with them because they were already packed "in a cooler or another box to take up there" but that on occasion she would unpack them once she arrived in Johnson City and that she saw "boxes with foreign languages on them." This objection is OVERRULED.

10. Paragraph 68 (Objection No. 38). This paragraph of the PSR reads: "Vanswaringen recalled a conversation in the Greeneville office with Kumar Sen and others during which they discussed the drugs being sent from overseas; Kumar Sen said that "'the volcano was holding them up.'" Vanswaringen actually testified that she heard Dr. Sen say a volcano "had erupted and the medicine could be slow." Dr. Sen stipulated that the volcano erupted in Iceland. An inference can certainly be drawn from this testimony that Dr. Sen knew the drugs were coming from overseas. In addition, physician's assistant Eric Chlebisch testified about delays or postponements of treatment during that time because flights from Europe were delayed and that he personally told Dr. Sen that they were not getting the necessary drugs because of the delays. This objection is OVERRULED.

11. Paragraph 72 (Objection No. 39). Dr. Sen objects to statements in this paragraph of the PSR that "Prior to 2009, Kumar Sen got upset when drugs did not show up and

yelled at the chemotherapy nurses” and that Eric Chlebisch discussed with Dr. Sen “delays due to the volcano in Iceland.” Dr. Sen argues these statements are inaccurate and inconsistent with Chlebisch’s trial testimony. There is nothing in Chlebisch’s testimony to indicate that Dr. Sen ever yelled at nurses. To that extent, the objection is SUSTAINED. The rest of the objected to statements of the PSR, however, are entirely consistent with the trial testimony and the objection is OVERRULED as to those.

12. Paragraphs 79 and 80 (Objections Nos. 45 and 46). In these objections, Dr. Sen takes issue with the probation officer’s description of Debbie Hurst’s testimony. He specifically takes issue with the last sentence of paragraph 79 which states that Hurst was told to look up NDC numbers on the internet if Tracy Gregg could not give her the numbers. He also disputes as inaccurate the statement in paragraph 80 that Dr. Sen “was concerned about a volcano or royal wedding delaying drugs from overseas suppliers.”

Hurst did testify that when she could not get an NDC number from Gregg or the chemotherapy room, she would get one from “Trish.” She also testified that there was a discussion in the office, in Dr. Sen’s presence, about “volcanos or the royal wedding and that they were needing a shipment in for a patient.” In response to a question about what the volcano or wedding had to do with that, Hurst testified: “I guess it would hold up the plane.” Hurst further testified that Dr. Sen asked Mrs. Sen “if the shipment had come in because he needed the drug.” To the extent the PSR’s statements are inconsistent with the above summary of Hurst’s testimony, the objection is SUSTAINED; otherwise, the objection is OVERRULED.

B. Offense Level/Guidelines Range

1. Base Offense Level/Downward Departure (Objection Nos. 47 and 52).

The probation office used USSG § 2N2.1 to determine the base offense level for a conviction under 21 U.S.C. § 331(a). Consistent with § 2N2.1, the officer has applied a base offense level of 6. The defendant does not dispute that § 2N2.1 is the correct guideline. Relying on Application Note 1, however, defendant argues that he was convicted of a status crime and the government “did not even attempt to prove negligence, knowing conduct, or reckless conduct,” entitling him to a downward departure and argues for a base offense level of 1. Application Note 1 reads: “This guideline assumes a regulatory offense that involved knowing or reckless conduct. Where only negligence is involved, a downward departure may be warranted.” USSG § 2N2.1, App. note 1. The government responds that Dr. Sen’s conduct was both knowing and reckless.

As an initial matter, it makes no difference whether the government attempted to prove knowing or reckless conduct at trial. It was not required to do so. In any event, it is generally beyond dispute and well settled that courts use a “preponderance of the evidence” standard in resolving factual disputes under the guidelines. *See* USSG § 6A1.3, Comment. *See also United States v. Worex*, 420 Fed. App’x 546, 550 (6th Cir. 2011) (“Since *Booker*, we have reaffirmed the doctrine that district judges in determining defendants’ sentences may consider facts that they find under a preponderance-of-the-evidence standard.”); *United States v. Sexton*, 512 F.3d 326, 330 (6th Cir. 2008) (“judicial fact-finding done by a preponderance of the evidence is permissible.”).

The question presented by the objection then is whether there is evidence by a preponderance in the record to support a finding that Dr. Sen acted recklessly or knowingly. Since the government did not chose to offer proof beyond the trial record, the Court looks to that record to make the determination. Initially, although Dr. Sen argues that his conviction here was

for a mere status offense lacking any negligence, knowing conduct or recklessness, the Court has little trouble finding his conduct to have been negligent. There is overwhelming proof in the record that he knew, or should have known, that his medical practice was using misbranded and unapproved drugs in violation of the law. Multiple witnesses testified that Dr. Sen was aware that drugs were being purchased from the overseas source but that he abdicated totally his responsibility as a medical doctor and owner of the practice when he delegated responsibility for day-to-day operations of the practice and supervision of the nurses and other personnel employed there to his co-defendant, who lacked any medical training whatsoever.

The question of whether his conduct was also reckless is a somewhat tougher question. Although §2N2.1 does not contain a definition of “reckless,” the term is defined in the commentary to § 2A1.4 (involuntary manslaughter) as “a situation in which the defendant was aware of the risk created by his conduct and the risk was of such a nature and degree that to disregard that risk constituted a gross deviation from the standard of care that a reasonable person would exercise in such a situation.” USSG § 2A1.4, App. note 1.³ In this case, there is little doubt that Dr. Sen, a well-trained and experienced medical specialist, was aware of the risk associated with the use of misbranded, non-FDA approved drugs in his oncology practice. Nor is there, in this Court’s opinion, much doubt that the risk was of such nature and degree as to constitute a gross deviation from the standard of care. Although Dr. Sen has always contended that no patient was harmed by use of the non-approved drugs, and no evidence has been presented that any patient was in fact harmed, such an argument misses the point. The much more important and pertinent inquiry is whether there was a risk of harm to patients from use of the non-approved drugs. There clearly was. FDA approval of drugs assures that drugs

³ The Sentencing Commission used the very same definition of reckless in § 3C1.2, suggesting that the same definition should be applied consistently throughout the Guidelines. In any event, the definition in § 2A1.4 comports with the traditional definition of recklessness.

administered to patients are safe and effective in terms of quality, strength and purity. Without the required FDA approval of drugs, neither the patients nor the professionals who administer them have the necessary information to assess the risks of the drug or its efficacy for its intended purpose. That is true here. While there is nothing to indicate that the unapproved drugs purchased by Dr. Sen's practice lacked the active ingredients of the approved drug, the chemotherapy nurses (and likely Dr. Sen himself if he had looked at the boxes and inserts), were unable to determine the strength or the recommended dosage for these unapproved drugs.

And, while nothing here suggests that Dr. Sen intended harm or was motivated by any improper purpose, he abandoned his duty and responsibility to assure that his patients received the drugs prescribed and in the dosage indicated to treat their life threatening conditions. Dr. Sen intentionally relinquished that duty to his practice manager, who lacked any medical training, and allowed her to instruct nurses on how to mix the unapproved drugs and she appears to have simply assumed that the drugs could be mixed and administered in the same strength and dosage as approved drugs. As the government argues, the fact “[t]hat it is impossible at this point to know exactly what was received and administered by Dr. Sen's practice re-emphasizes the importance of the [Food, Drug & Cosmetic Act]'s closed regulatory scheme-where drugs are tracked from the manufacturer, through wholesalers, and eventually to the provider and patient-and the dangers created by introducing unapproved drugs into the U.S. healthcare system.” Dr. Sen's conduct was reckless and his objection is OVERRULED and his request for a downward departure is DENIED.

2. Mitigating Role

Section 3B1.2 of the Sentencing Guidelines provides for a four level decrease in the offense level “[i]f the defendant was a minimal participant in any criminal activity” and a

two-level decrease “[i]f the defendant was a minor participant.” USSG § 3B1.2(a) and (b). “The defendant, who is the proponent of the downward adjustment, bears the burden of proving a mitigating role in the offense by a preponderance of the evidence.” *United States v. Roberts*, 223 F.3d 377, 379 (6th Cir. 2000) (citing *United States v. Owusu*, 199 F.3d 329, 337 (6th Cir. 2000)). According to Dr. Sen, the proof at trial demonstrated that “he was never involved in ordering the drugs in question, never administered them, and never even saw them.”⁴

Before the mitigating role downward adjustment provided for in § 3B1.2(a) or (b) can be applied to Dr. Sen, he must prove that he is “*substantially* less culpable than the average participant.” USSG § 3B1.2, App. note 3(A) (emphasis added). The determination is a fact-based one “based on the totality of the circumstances” and “heavily dependent on the facts of the particular case.” *Id.*, App. note 3(C). “[L]ack of knowledge or understanding of the scope and structure of the enterprise and the activities of others is indicative of a role as a minimal participant.” *Id.* App. n.4.

The Court concludes, however, that Dr. Sen has failed to prove his entitlement to the mitigating role adjustment. The government has conceded that “Dr. Sen was less culpable than Mrs. Posey,”⁵ but argues that the higher sentencing guidelines range for her reflects that. Although Dr. Sen claims that the proof at trial established his minimal role, he has offered no positive proof of his entitlement to the adjustment and the Court concludes that, at best, all that can be said of the proof at trial is that none was offered by the government to establish that Dr. Sen was not involved in the ordering of the drugs, in administering the drugs, or that he ever saw

⁴ Dr. Sen’s argument here only confirms what the Court has said about the reckless nature of his conduct in the prior section.

⁵ This concession is not binding on the Court at sentencing and the Court questions its accuracy. The question of whether Mrs. Sen, untrained in medical field, is more culpable here than Dr. Sen, a medical professional who simply abdicated his duty and responsibility, is highly debatable.

them. Defendant's position here brings to mind the old aphorism⁶ "absence of evidence is not evidence of absence." The burden is on Dr. Sen to offer positive evidence that entitles him to the adjustment, a burden conceptually distinct from a lack of evidence. Dr. Sen has not met his burden and this objection is OVERRULED.

C. Constitutional Bar on Imprisonment

In objections 49, 50 and 51, Dr. Sen objects to paragraphs 133, 141 and 143 of the PSR because they omit any mention of what he claims is a constitutional bar on imprisonment for status crimes that do not require proof of a *mens rea*, *i.e.* which impose strict liability, relying on *Staples v. United States*, 511 U.S. 600, 616-17 (1994) and *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 476 (1933) and that fines in such cases are "generally small," relying on *Morrisette v. United States*, 342 U.S. 246, 254-56 (1952). These arguments do not affect the guidelines range and are more appropriately addressed by the Court in determining what sentence is "sufficient, but not greater than necessary, to comply with the purposes set forth" in 18 U.S.C. § 3553(a)(2). The PSR correctly states the statutory maximum imprisonment authorized by Congress per count for violation of 21 U.S.C. § 331(a), that is, one year. Defendant also objects to the fine range set forth by the probation officer in paragraph 143. The probation officer agrees with the defendant that the guidelines fine range is from \$500 to \$5,000, pursuant to USSG § 5E1.2(c)(3). Dr. Sen's objection with respect to paragraphs 138 and 141 are OVERRULED. Dr. Sen's objection with respect to paragraph 143 is SUSTAINED in part.

D. Variance

In objection No. 53, Dr. Sen objects to the probation officer's statement in paragraph 150 of the PSR that "[t]he probation officer has not identified any factors that would warrant a variance from the applicable sentencing guideline range," suggesting that there are "multiple

⁶ The term "aphorism" was, ironically, first used in the *Aphorisms of Hippocrates*.

factors that would warrant a variance from the applicable sentencing guidelines range.” This objection also does not affect the applicable guidelines range and defendant is free to advance this argument at sentencing.

E. Conclusion

In short, except as modified herein, the Court will adopt the PSR prepared by the probation officer as its FINDINGS. The defendant’s offense level is 6, his criminal history category is I, and the advisory guidelines range is 0 to 6 months. The guidelines range for a fine is from \$500 to \$5,000. By statute, Dr. Sen faces a maximum term of one year of imprisonment as to each count and a maximum fine of \$100,000 for each count.

II. Mrs. Sen’s Objections

Mrs. Sen has filed 14 separately numbered objections which overlap somewhat with Dr. Sen’s. Each will be addressed below.

A. Paragraphs 9 – 80 (Objection No. 1). Mrs. Sen makes much the same general objections to the offense conduct section of the PSR as does Dr. Sen. According to Mrs. Sen, these paragraphs “make assertions that are incorrect, incomplete, and/or inconsistent with the factual record” and “omit multiple events and points of information which are highly relevant to sentencing for the current offenses of conviction, and they include multiple accusations and assertions of an intent by the defendant to mislead, misinform, lie, deceive, and circumvent the law.” Mrs. Sen notes that these “accusations and assertions were presented by the prosecution at trial, and the jury did not find sufficient proof for a single one of them . . .”

Mrs. Sen does not specifically address the portions of these paragraphs which she asserts are incorrect, misleading, or inaccurate based on the trial record nor does she submit what she

thinks is an accurate summary of the proof at trial, choosing to rely instead on the arguments made in objections 3 through 46 by Dr. Sen. For that reason, the Court will not address these objections beyond what it has already said in response to Dr. Sen's objections.

B. Paragraph 81 (Objection No. 2). Mrs. Sen objects to the victim impact portion of the PSR. She argues that the paragraph should simply say "there are no identifiable victims in this case." She specifically objects to the probation officer's statement that ETCBC engaged in "furtive movements" to obtain drugs from foreign sources, and that ETCBC submitted false claims to 10 health care benefit programs. The use by the probation officer of the phrase "furtive movements" was likely a poor choice of words to describe the conduct related in this section of the PSR, and the Court will deal with Mrs. Sen's claim that she engaged in no intentional wrong doing or deception in a later section of this memorandum. This part of Mrs. Sen's objection will be SUSTAINED and the reference to "furtive movements" will be deleted from the PSR. The objection as to the remaining portions of the paragraph, however, will be OVERRULED. Proof at trial did establish, certainly by a preponderance of the evidence, that 8 identifiable patients received Altuzan rather than Avastin and that false claims for unapproved drugs were submitted to at least 10 health care benefit programs.

C. Paragraph 82 (Objection No. 3). Paragraph 82 of the PSR accurately describes the provisions of USSG § 3C1.1 dealing with obstruction of justice. Defendant acknowledges that but argues the paragraph should be stricken because it has no application to her case. The Court will address the application of the obstruction guideline to Mrs. Sen's case below. This objection is OVERRULED.

D. Paragraph 83 (Objection No. 4). As this paragraph of the PSR indicates, the United States served a subpoena on East Tennessee Hematology Oncology (a/k/a ETCBC) which

sought, among other things, any correspondence between any employee of the practice and Clinical Care. On May 15, 2012, Derek Johnson of Digital Forensics, who had been retained by defendants “to conduct a preliminary survey of the computers and electronic data storage systems at the clinic at Greeneville,” turned over responsive documents to FDA Agent Robert J. West. During the trial of this case, Mr. Warlick, attorney for Mrs. Sen, produced e-mail messages between Mrs. Sen and Kim Cole of Clinical Care.⁷ These e-mails were not among the materials produced to Agent West. Defendant objects to paragraph 83 first on the basis that Mr. Johnson spent several days at the clinic copying electronic records and provided the results of his search directly to Agent West, apparently suggesting by inference that Mr. Johnson was responsible for not identifying and producing the documents. At the hearing on this objection, however, Mr. Johnson testified that he relied on employees of the practice to provide documents responsive to the subpoena, and the e-mails at issue were not provided to him.

The probation officer’s statement in the PSR indicates that there were two e-mail messages produced by Mr. Warlick at trial dated March 1, 2012 and March 2, 2012. Mrs. Sen says that “[i]n actuality, **three** e-mail messages were referenced at trial.” She is correct on that score and the PSR should reflect the correct number of e-mails. Otherwise, the objection is OVERRULED.

E. Paragraph 84 (Objection No. 5). Paragraph 84 of the PSR correctly recites the provisions of Application Note 4(D) of USSG § 3C1.1 that “destroying or concealing or directing or procuring another person to destroy or conceal evidence that is material to an official investigation . . .” is an example of conduct which constitutes obstruction of justice and applies the two level enhancement pursuant to USSG § 3C1.1. Once again, the paragraph correctly

⁷ Mr. Warlick proposed to cross examine Agent West by using the e-mails. After the government objected that the e-mails had not been produced by the defendant pursuant to the subpoena, Mr. Warlick simply withdrew them. The Court was never asked to rule on the government’s objection and the e-mails were not made part of the trial record.

states the content of the Application Note and the Court will fully address the application of the guideline provision to Mrs. Sen's case below. This objection is OVERRULED.

F. Paragraphs 88, 89, 90 and 91 (Objection Nos. 6 and 7). In paragraph 88 of the PSR, the probation officer identifies § 2N2.1 of the guidelines as providing the base offense level for a violation of 21 U.S.C. § 331(a). That section also instructs that § 2B1.1 be applied if the offense involved fraud. The probation officer applied the base offense level from § 2N2.1 in paragraph 88 and increased the offense level based on three specific offense characteristics from § 2B1.1-18 levels pursuant to § 2B1.1(b)(1)(J) for loss of more than \$2.5 million, two levels pursuant to § 2B1.1(b)(2)(A) because the offense involved more than 10 victims, and two levels pursuant to § 2B1.1(b)(7) because the offense involved an offense involving a government health care program which suffered a loss greater than \$1,000,000.

Mrs. Sen apparently objects to the cross reference to §2B1.1 on two basis; (1) the cross reference does not apply because Mrs. Sen was acquitted of the charged felony violation of 21 U.S.C. § 331(a) which required the government to prove an intent to defraud or mislead, and (2) the Statutory Index, Appendix A to the Guidelines Manual, indicates that § 2N2.1 is to be applied when the conviction is a misdemeanor under 21 U.S.C. § 331(a) and the cross reference to § 2B1.1 is to be applied only where there is a felony conviction under § 331(a)(2).

1. Acquitted Conduct.

Defendant's argument that the government is required to prove fraud to a jury beyond a reasonable doubt and that the jury's verdict of not guilty on the counts alleging fraud preclude the application of § 2B1.1 is without merit. Regardless of the jury's acquittal, and the perceived unfairness of applying the guidelines under those circumstances on the fraud counts, the Sixth Circuit has made it abundantly clear that a district court is not precluded from looking

to other facts, including acquitted conduct, when selecting a sentence or when basing offense level enhancements on acquitted conduct. In *United States v. White*, a defendant convicted of armed robbery and possessing a firearm with the serial number removed challenged, on Sixth Amendment grounds, the district court's reliance on acquitted conduct to support sentencing guidelines offense level enhancements. 551 F.3d 381 (6th Cir. 2008) (en banc). The Sixth Circuit held that “[s]o long as the defendant receives a sentence at or below the statutory ceiling set by the jury's verdict, the district court does not abridge the defendant's right to a jury trial by looking to other facts, including acquitted conduct, when selecting a sentence within the statutory range.” *Id.* at 385. Noting that the jury's verdict of not guilty did not establish that the defendant did not commit the crime, but rather “it says something very different—that the conduct had not been proved beyond a reasonable doubt,” *id.* the en banc Sixth Circuit held that “consideration of acquitted conduct at sentencing passes constitutional muster” if “enhancements based on acquitted conduct do not increase a sentence beyond the maximum penalty provided by the United States Code.” *Id.* at 386. The defendant's objection on this basis must be OVERRULED since this Court is bound by Sixth Circuit precedent.

Peculiarly, Mrs. Sen does not argue that the proof at trial does not establish by a preponderance of the evidence that the offense involved fraud. Likely because the defendant did not challenge whether the evidence preponderates in favor of a finding of fraud, the government gives very little attention to the matter in its sentencing memorandum, simply arguing in a conclusory fashion that Mrs. Sen “acted to defraud health care benefit programs by causing false claims for unapproved drugs to be submitted to . . . health care benefit programs.” The government specifically asserts that she acted with intent to mislead the practice's patients by concealing use of unapproved drugs and affirmatively represented to patients through a sign

posted in the chemotherapy room that only FDA approved drugs were used. She further, according to the government, misrepresented to the health care benefit care programs that approved drugs were administered by using procedure codes applicable to the approved drugs.

Despite the only superficial treatment of the question by the parties, however, the Court will nevertheless, by reference to the trial transcripts, examine the question more closely. The evidence in the case established, by a preponderance, that Mrs. Sen was aware that only FDA approved drugs could be used in the practice. She inquired of the Clinical Care representative on one occasion as to whether a drug was FDA approved and she had a sign posted in the chemotherapy room reassuring patients that the practice used only FDA approved drugs. The proof in the case clearly establishes that it was Mrs. Sen who was given absolute authority in the practice to order drugs. Mrs. Sen began to order drugs from Clinical Care, a company she knew to be located outside the United States, rather than from Oncology Supply in order to save money, and received drugs from overseas that did not bear the name of a U.S. drug product. There is nothing in the record which establishes that Mrs. Sen made any effort to determine whether the drugs were approved, information that she could have easily obtained on the internet. Some of these drugs, when received, did not bear labeling on the packages or inserts which were written in English. When the nurses could not read the directions on the package because they were in foreign languages, Mrs. Sen, who lacked any medical training whatsoever, instructed the nurses to administer the unapproved drugs in the same dosage as the approved drugs. Mrs. Sen, also in charge of billing, submitted claims for reimbursement to health care benefit programs for reimbursement for the FDA approved version of the drug with knowledge, or at least deliberate indifference, that the practice could not be reimbursed for use of unapproved drugs. Since reimbursement rates were based on the approved versions of the drugs,

and the unapproved drugs were not eligible for reimbursement at all, the practice benefited financially from the lower prices paid for the unapproved version. By a preponderance of the evidence, the Court FINDS that Mrs. Sen acted with intent to defraud.

2. Specific Offense Characteristics

The defendant objects to the enhancements to the offense level based on the specific offense characteristics from § 2B1.1, arguing simply that they result “from the incorrectly applied USSG § 2B1.1.” Beyond that, she did not address whether the factual basis for the enhancements was established by a preponderance of the evidence. Nonetheless, the Court will address each briefly.

a. USSG § 2B1.1(b)(1)

The offense level under §2B1.1(b)(1) increases with the amount of the loss. “Loss” is defined in the commentary to the guideline as the greater of the actual or intended loss and “actual loss” is defined as “the reasonably foreseeable pecuniary harm that resulted from the offense.” USSG § 2B1.1, App. note 3(a). The evidence at trial established that the practice submitted approximately \$3.2 million in false claims for unapproved drugs. Since none of these claims were properly reimbursable by health care benefit programs, see 42 U.S.C. § 1395x(t), the amount of false claims establishes the amount of loss for §2B1.1 purposes and the 18 level increase in the offense level pursuant to § 2B1.1(b)(1) is appropriate.

b. USSG § 2B1.1(b)(1)(J)

The offense level under § 2B1.1 also increases based on the number of victims. Here it is undisputed that there were at least 10 health care benefit program victims and at least 8 identifiable patients who received Altuzan rather than Avastin and the two level increase in offense level of § 2B1.1(b)(1)(J) applies.

c. USSG § 2B1.1(b)(7)

Section 2B1.1(b)(7) provides for a two-level increase in the offense level if the defendant was convicted of a “Federal health care offense” and losses to government health care benefit programs exceeded one million dollars. Violations of 21 U.S.C. § 331 are specifically identified as federal health care offenses, see 18 U.S.C. § 24, and losses to the government programs clearly exceeded one million dollars. The enhancement applies.

G. Appendix A

Mrs. Sen also argues, without citation to any authority, that the structure of the guidelines manual prohibits a cross reference to § 2B1.1 in her case. The statutory index (Appendix A) to the United States Sentencing Guidelines Manual provides the reference to the appropriate guidelines section(s) based on the offense of conviction. In the index, the manual’s reader is directed to § 2N2.1 for convictions under 21 U.S.C. § 331(a). For convictions under 21 U.S.C. § 333(a)(2) for violation of § 331(a) involving fraud, the index directs the reader to both §§ 2N2.1 and 2B1.1, suggesting, according to defendant, that the cross reference to §2B1.1 does not apply unless the crime of conviction was for a felony under § 333(a)(2).

On the surface, the argument has some logic. Nothing in the text or commentary of §2N2.1, however, suggests that the Sentencing Commission intended to limit the guideline in the manner suggested by the defendant. The Commission could easily have provided in the text of the guideline or in the Application Notes that the cross reference to § 2B1.1 applies only where there is a conviction under § 331(a) and 333(a)(2). They chose not to do so. Furthermore, it appears that the Sixth Circuit’s en banc decision in *White*, discussed above, also dooms the argument. Relying on the United States Supreme decision in *United States v. Watts*, the Sixth Circuit held “that a jury’s verdict of acquittal does not prevent the sentencing court from

considering conduct underlying the acquitted charge, so long as that conduct has been proved by a preponderance of the evidence.” *White*, 551 F.3d at 383 (quoting *United States v. Watts*, 519 U.S. 148, 157 (1997) (per curiam)).

The Court has located one case decided by a district court in the Sixth Circuit involving § 2N2.1 which sheds some light on the issue as well. In *United States v. Coleman*, three defendants were convicted of misdemeanor violations of 21 U.S.C. § 331(a) without intent to defraud or mislead, as the Sens were convicted here. 370 F. Supp. 2d 661 (S.D. Ohio 2005). At sentencing, the government argued that the fraud enhancement of § 2N2.1(b)(1) should be applied because the government had successfully proved fraud by a preponderance of the evidence. *Id.* at 668. The district court held that “acquitted conduct should always be considered using a reasonable doubt standard,”⁸ *id.* at 368, and refused to apply the cross reference. The district court’s decision was not appealed.

Even before the Sixth Circuit’s en banc decision in *White*, however, the Sixth Circuit had rejected the reasoning of *Coleman* in another case decided by the same district judge. In *United States v. Brika*, the defendant relied on *Coleman* to support his argument that a reasonable doubt standard applies at sentencing. 487 F.3d 450 (6th Cir. 2007). The Sixth Circuit found that *Coleman* had no impact on *Brika*’s case because it dealt with acquitted conduct, rather than conduct on which the jury could not agree, which was the situation in *Brika*. *Id.* at 460. Nevertheless, the Sixth Circuit expressed its disagreement “with the substantive outcome of [Coleman] in light of *Watts*. *Id.* It seems then, in light of *Brika*, that a district court shall determine whether to apply the cross reference of § 2N1.1 by applying a preponderance of the evidence standard in deciding whether the offense involved fraud regardless of whether the jury

⁸ The district court also held that fraud had not been proven by the lesser preponderance of the evidence standard.

acquitted the defendant of the felony offense. Any doubt about that was eliminated by the en banc *White* decision.

In light of these binding precedent, the probation officer's approach to the cross reference was proper and defendant's objections are OVERRULED.

H. Paragraph 94 (Objection No. 8). In paragraph 94 of the PSR, the probation officer applied the two-level increase in the offense level from USSG § 3C1.1 for obstruction of justice. First, the probation officer found obstruction on the basis that Mrs. Sen withheld evidence during the discovery process, as described in paragraph 83 of the PSR. Second, the probation officer found obstruction related to the return of certain medications to the United Kingdom, also described in paragraph 83.

United States Sentencing Guidelines § 3C1.1 provides for a two-level increase in the offense level “[i]f (1) the defendant willfully obstructed or impeded, to attempted to obstruct or impede, the administration of justice with respect to the investigation, prosecution, or sentencing of the instant offense of conviction, and (2) the obstructive conduct related to (A) the defendant’s offense of conviction and any relevant conduct; or (B) a closely related offense . . .” Of relevance here also is Application Note 1 from the commentary to the guideline:

Obstructive conduct that occurred prior to the start of the investigation of the instant offense of conviction may be covered by this guideline if the conduct was purposely calculated, and likely, to thwart the investigation or prosecution of the offense of conviction.

1. Concealment of Subpoenaed Documents

The facts relevant to this objection are relatively undisputed and set out in paragraph II. D. above. Mrs. Sen argues that the PSR incorrectly implies that the e-mails were purposefully withheld by the defendant and that the failure to produce the documents was not

“purposefully calculated . . . to thwart the investigation or prosecution of the offense of conviction.” Mrs. Sen does not contest that the e-mails were not produced to Agent West or that they were not required to be produced. Mr. Warlick candidly informed the Court at the hearing on these objections that he had not seen the e-mails until they were produced by his client on December 9, during the trial. Mr. Johnson testified, without contradiction, that he relied upon the employees to produce the responsive e-mails and that he turned over to Agent West all that he was provided.

The commentary to § 3C1.1 notes that “[o]bstructive conduct can vary widely in nature, degree of planning, and seriousness.” USSG § 3C1.1, App. note 3. Examples of obstructive conduct include “ . . . concealing . . . evidence that is material to an official investigation or judicial proceeding.” *Id.*, App. note 4(D). The withholding of documents responsive to a subpoena can constitute obstructive conduct. *United States v. Gray*, 521 F.3d 514, 515 (6th Cir. 2008); *United States v. Rasheed*, 663 F.2d 843, 852-53 (9th Cir. 1981).

The defendant suggests that she would not have withheld the e-mails intentionally because they were exculpatory in nature. The government disagrees and so too does the Court. An inference can easily be drawn from the e-mails that Mrs. Sen was aware of the fact that the practice had obtained counterfeit drugs, and they were returned to the United Kingdom to put them out of the reach of FDA investigators or other authorities. In any event, the e-mails were clearly required to be produced in response to the subpoena. Further, the fact that Mrs. Sen had the e-mails in her possession on December 9 for use by her attorney in cross examination if needed also refutes her claim that failure to produce the e-mails was inadvertent or unintentional. Applying the preponderance of the evidence standard, the Court FINDS that Mrs. Sen intentionally withheld and concealed e-mails responsive to the subpoena that were material to an

official investigation. The probation officer properly applied the two-level enhancement for obstruction of justice pursuant to § 3C1.1.

2. Return of Medications to the UK

Tammy Seabolt, Accounts Receivable Clerk at the Greeneville Clinic, heard on the news a report in regard to McLeod Cancer Center relative to the use of counterfeit and/or unapproved drugs. Ms. Seabolt does not remember the exact date of that news report. After hearing the news report, Ms. Seabolt shared that information with Larry Edgell and the chemotherapy nurses. About the same time, Mrs. Sen caused certain drugs purchased from Clinical Care to be returned. The government suggests that the action taken by Mrs. Sen was an effort to obstruct justice in that her actions would make impossible the inspection of the drugs by FDA. The government here has not clearly established through either testimony or exhibits a sequence of these events from which the Court could make a finding of obstruction of justice. Although Mrs. Sen's actions appear suspicious, the Court cannot find by a preponderance of the evidence that she returned the drugs because she knew they were counterfeit drugs and in an effort to prevent the government's access to the drugs. In any event, in light of the Court's finding with respect to the withheld documents, it is unnecessary for the Court to decide this objection.

I. Paragraphs 95, 98, 140 and 143 (Objection Nos. 9 and 11). In these objections, Mrs. Sen maintains that the guidelines calculations and fine range in paragraphs 95, 98, 140 and 147 contain a calculation based on the incorrectly applied USSG § 2B1.1. Given the Court's ruling as to objection Nos. 6 and 7, these objections are OVERRULED.

J. Paragraphs 134, 135 and 141 (Objection Nos. 10 and 12). In these objections, defendant raises the same issue raised by Dr. Sen in his objection No. 49, i.e., that there is a

constitutional bar on imprisonment for status crimes which do not require proof of *mens rea* and that the fines for regulatory crimes are relatively small. This Court need not decide whether Mrs. Sen is correct about the constitutional bar; even assuming arguing though that there is such a constitutional bar, Mrs. Sen's crime was not such a status crime.

The jury in this case was charged that there were two ways the crime of introduction of misbranded drugs into interstate commerce could be committed: First, that the government could prove that the defendant personally caused the introduction of misbranded drugs into interstate commerce, that is, that the defendant did some act or acts that caused misbranded drugs to be moved in interstate commerce, and second, that a defendant held a position of responsibility. The government did not argue the second theory of liability as to Mrs. Sen, and it is clear that the jury found beyond a reasonable doubt that she "caused" the introduction of misbranded drugs. It does not seem therefore that Mrs. Sen's crime was a "status crime." In other words, Mrs. Sen was not convicted merely because of her status, i.e., her position of responsibility. Rather, she was convicted based on what she had done, i.e. caused.

In any event, as noted above, when dealing with Dr. Sen's identical objection, these objections do not affect the guidelines calculations and need not be resolved in the context of this objection. Defendant is free to make her arguments to the Court when it addresses the question of what sentence, both of imprisonment and fine, is "sufficient, but not greater than necessary." The objections are OVERRULED.

K. Paragraphs 149 and 150 (Objection No. 14). The defendant objects to these paragraphs because they omit the language of Application Note 1 of § 2N2.1. *See* § I.B.1 above. She specifically argues that "the government did not prove knowing or reckless conduct in the

present case,” and she is therefore entitled to a downward departure or variance on that basis. The Court disagrees.

The proof offered at trial by the government was, in the Court’s view, more than ample to establish, at a minimum, both knowing and reckless conduct on Mrs. Sen’s part. Numerous witnesses testified that Mrs. Sen was in complete control of the day-to-day operations of the clinic, was responsible for hiring staff, including nurses, and was responsible for ordering the chemotherapy drugs. Until 2009, the practice ordered all of its drugs from Oncology Supply and ordered only FDA approved drugs. In 2009, however, Mrs. Sen made a decision to order some of the drugs from Clinical Care, in order to get a better price on the drugs (which increased the practice’s profit because of the way health care benefit programs reimburse for the use of these drugs).

There is no convincing proof in the record that Mrs. Sen made any investigation of Clinical Care or whether the drugs from Clinical Care were FDA approved, or even of the same quality and to be administered in the same dosage as the FDA approved drugs, before purchasing them. Indeed, the only proof on that question would suggest that Mrs. Sen simply accepted the self-serving assurances of Clinical Care’s salesman. There is no proof that she ever discussed the change with Dr. Sen, the owner of the practice, and the only person with the training and expertise to make such a decision. The proof established that she simply instructed the chemotherapy nurses to mix and administer the drugs in the same way as the FDA approved versions when the directions on the packages or inserts could not be read and understood because they were in a foreign language. Despite her lack of medical training and qualifications to make such a decision, nothing suggests that she ever consulted the practice owner and the only licensed oncologist in the practice before making such a decision.

The government has proven, by a preponderance of the evidence, that Mrs. Sen's conduct was both knowing and reckless and her objection is OVERRULED.

L. Conclusion

In sum, except as modified herein, the Court will adopt the PSR prepared by the probation officer as its findings in Mrs. Sen's case. Defendant's offense level under the guidelines is 30, her criminal history category is I, and the guideline range for imprisonment is 97 to 121 months. The guideline range for a fine is from \$15,000 to \$150,000 pursuant to United States Sentencing Guideline § 5E1.2(c). By statute, Mrs. Sen faces a maximum term of one year of imprisonment for each count and a maximum fine of \$100,000 for each count.

So ordered.

ENTER:

s/J. RONNIE GREER
UNITED STATES DISTRICT JUDGE